DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

MEDICAL DEVICE REPORTING ANNUAL USER FACILITY REPORT

OMB: 0910-0437 Exp. Date: 05/31/2009

CDRH Medical Device Reporting P.O. Box 3002 Rockville, MD 20847-3002

PART 1 - COVER SHEET

If MDR reports were not submitted to either the FDA or a device manufacturer during this reporting period, DO NOT submit an annual report.

PART 1 INSTRUCTIONS Complete one copy of the following information as a cover page for the annual report and return to the address listed above. This report should NOT include reports that are not required but have been submitted voluntarily. 1. REPORT PERIOD 2. USER FACILITY ID (HCFA OR FDA PROVIDED NUMBER)

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3. USER FACILITY INFORMATION	ON		4. L	JSER FAC	ILITY CON	TACT INFORMA	TION	
a. Name			а	. Name				
b. Street Address				. Street A	ddress			
c. City	3. 3	ZIP Code		. City		d. S	tate	e. ZIP Code
f. Country/Postal Code (if not	U.S.)					e (if not U.S.)		
			g	. Telepho	ne Number ((Include area cod	de and extens	ion)
5. TOTAL NUMBER OF REPORTS ATTACHED OR SUMMARIZED								
a. Lowest Report Number _	(HCFA or FDA Provided No.)			Seque	ence No.)			
b. Highest Report Number _	(HCFA or FDA Provided No.)	_ - _	(Year)	(Seque	ence No.)			
For each report in the range of report numbers listed above, attach a completed copy of Part 2 of this form, or a photocopy of the completed MedWatch FDA Form 3500A for the event that was sent to FDA and/or the manufacturer. In addition, attach a sheet listing report numbers in the above range that are not included in this report and explain why.								
6. SIGNATURE OF CONTACT				7.	DATE OF R	EPORT		

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Center for Devices and Radiological Health Office of Surveillance and Biometrics Division of Surveillance Systems, RSMB, HFZ-533 1350 Piccard Drive Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

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PART 2 - SUMMARY OF EVENT

PART 2 INSTRUCTIONS

If photocopies of previously submitted FDA Form 3500A (MedWatch) are not provided for each MDR reportable event, complete one copy of the following for each MDR report submitted to FDA and/or the manufacturer during the calendar year covered by this Annual Report.

the calendar year covered by this Annual Report.							
1. USER FACILITY EVENT REPORT NUMBER							
<u>-</u>	_						
(HCFA or FDA Provided No.)	(Year) (Sequence No.)						
2. WHERE WAS REPORT SUBMITTED? (Check all that apply)							
☐ FDA ☐ Manufacturer ☐ Distributor ☐ Other .							
3. MANUFACTURER INFORMATION	4. DEVICE INFORMATION						
a. Name	a. Brand Name						
	b. Common Name						
b. Street Address							
2. G. 100. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1.	c. Model Number						
0.5							
c. City d. State e. ZIP Code	d. Serial Number						
	e. Lot Number						
f. Country/Postal Code (if not U.S.)	C. Ostalan Marshar						
	f. Catalog Number						
5. BRIEF DESCRIPTION OF EVENT							